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Re-evaluation Decision RVD2014-04

Clofentezine

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Re-evaluation Decision

Clofentezine is an ovicidal acaricide. Two clofentezine products are currently registered in Canada under the authority of the *Pest Control Products Act*, including one technical grade active ingredient and one commercial class end-use product.

After a re-evaluation of clofentezine, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act*, is granting continued registration of products containing clofentezine for sale and use in Canada. An evaluation of available scientific information found that products containing clofentezine do not present unacceptable risks to human health or the environment when used according to the conditions of registration, which include amended label directions. Clofentezine was found to have value as an acaricide. As a condition of the continued registration of clofentezine, label amendments are required for all end-use products. Appendix I lists the required label amendments. No additional data are requested at this time.

This re-evaluation decision,[1] previously proposed in the consultation document, Proposed Re-evaluation Decision PRVD2013-05, *Clofentezine*, describes the decision-making stage of the PMRA's regulatory process and summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. Therefore, this decision is consistent with the proposed re-evaluation decision stated in PRVD2013-05. Please refer to PRVD2013-05 for the detailed 'Science Evaluation' of the human health, environmental and value considerations underlying the re-evaluation decision. A reference list for all data used as the basis for the re-evaluation decision is also included in PRVD2013-05.

To comply with this decision, registrants of clofentezine products will be informed of the specific requirements affecting their product registration(s) and of the regulatory options available to them.

Other Information

Any person may file a notice of objection[2] regarding this decision on clofentezine within 60 days from the date of publication of this Re-evaluation Decision document. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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1 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

2 As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing Clofentezine

The following label amendments are required for technical and end-use products as applicable.

A) Label Changes Relating to Human Health

Additional information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers.

PRECAUTION STATEMENTS:

Add:

Apply only when the potential for drift to areas of human habitation or areas of human activity (e.g. houses, cottages, schools and recreational areas) is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment and sprayer settings.

Not for use in greenhouses.

RESTRICTED-ENTRY INTERVAL:

The restricted-entry intervals (REIs) listed in the table below must be added to end-use product labels. Where deemed necessary, REIs are sub-divided according to re-entry activities.

Required Restricted Entry Intervals

Crop	Activity	REI
Apples, Pears, Peaches, Nectarines	Hand Thinning	2 days
	All Other Activities	12 hrs
Raspberries	Hand Pruning, Training, Tying	10 days
	All Other Activities	12 hrs
Strawberries	All Activities	12 hrs
Outdoor Deciduous Nursery Stock	All Activities	12 hrs

Add to DIRECTIONS FOR USE:

Do not harvest within 21 days after application.

A minimum rotational crop plantback interval of 12 months must be observed for all crops other than those registered for use with clofentezine.

B) Label Changes Relating to Environment

Label Amendments for Clofentezine Technical Insecticide

Add the following statements before the section entitled **STORAGE:**

ENVIRONMENTAL HAZARDS:

> *TOXIC to birds*
> *TOXIC to small mammals*
> *TOXIC to aquatic organisms*

Remove the following statement under the "**DISPOSAL AND DECONTAMINATION**" section:

> *Canadian formulators of this technical should dispose of unwanted active and containers in accordance with municipal or provincial regulations. For information on disposal of unused, unwanted product, contact the manufacturer or the provincial regulatory agency. Contact the manufacturer and the provincial regulatory agency in the case of a spill, and for clean-up of spills.*

And **Replace** with the following statement:

> *Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and clean-up of spills, contact the manufacturer or the provincial regulatory agency.*

Label Amendments for Commercial Class Products Containing Clofentezine

Add to ENVIRONMENTAL HAZARDS:

> *TOXIC to birds*
> *TOXIC to small mammals*
> *TOXIC to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE.*
>
> *To reduce runoff from treated areas into aquatic habitats, do not apply to areas with a moderate to steep slope, compacted soil or clay.*
>
> *Do not apply when heavy rain is forecast.*
>
> *Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body.*

Add to GENERAL DIRECTIONS FOR USE:

The following statements are required for all agricultural and commercial pesticide products:

> ***DO NOT*** *use to control aquatic pests.*
>
> ***DO NOT*** *contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.*
>
> ***DO NOT*** *apply by air.*

For **field applications using conventional boom sprayers** (agricultural or commercial products), the following statements are required:

> *Field sprayer application:* ***DO NOT*** *apply during periods of dead calm.* ***DO NOT*** *apply this product when winds are gusty.* ***DO NOT*** *apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE) medium classification. Boom height must be 60 cm or less above the crop or ground.*

For **airblast applications** (agricultural or commercial products), the following statements are required:

> *Airblast application:* ***DO NOT*** *apply during periods of dead calm.* ***DO NOT*** *apply this product when winds are gusty.* ***DO NOT*** *direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows.* ***DO NOT*** *apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.*

The following buffer zone statements and table are required to be added:

> ***Buffer Zones:***
> *Use of the following spray methods or equipment* ***DOES NOT*** *require a buffer zone: hand-held or backpack sprayer and spot treatment.*
>
> *The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive estuarine/marine habitats.*

Buffer Zones for the Protection of Aquatic Life from Spray Drift of Clofentezine

Method of application	Crop		Buffer Zones (metres) Required for the Protection of:	
			Estuarine/Marine Habitats of Depths:	
			Less than 1 m	Greater than 1 m
Field sprayer	Strawberry, raspberry		1	1
Airblast	Apple, pear, peach, nectarine	Early growth stage	5	2
		Late growth stage	3	1

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

C) Label Changes Relating to Value

Label Amendments for Commercial Class Products Containing Clofentezine

Under **DIRECTIONS FOR USE, Use on Apples and Pears**, the following statements below must be **removed:**

Target Species:
European red mite (*Panonychus ulmi*), Twospotted spider mite (*Tetranychus urticae)*, McDaniel spider mite (*Tetranychus mcdanieli*).

Apply with ground equipment using either dilute or concentrate sprays. Apply 300–600 mL APOLLO® SC OVICIDAL MITICIDE per hectare. When high dilution rate is used (3800 litres or more of water) use no less than 75 mL of APOLLO® SC OVICIDAL MITICIDE per 950 litres of spray. Use sufficient volume of water to obtain complete coverage but not less than 475 litres per hectare. Do not use less than 300 mL of APOLLO® SC OVICIDAL MITICIDE per hectare in concentrate sprays. APOLLO® SC OVICIDAL MITICIDE works best applied to eggs or young motile stages. It is not effective against adults.

Apples
APOLLO® SC OVICIDAL MITICIDE may be applied any time from delayed dormant through first cover. Best results in early season will be obtained if treatments are made at petal fall before mites hatch. Do not apply after first cover (provided first cover is not more than 14 days after petal fall).

Pears
APOLLO® SC OVICIDAL MITICIDE may be applied early season (after delayed dormant) through to summer. Apply at first sign of mite activity when mite populations are predominantly in the egg stage, with few early motiles (less than 3 per leaf). Do not apply within 21 days of harvest.

NOTE:
Factors which may warrant consideration of rates higher than 300 mL APOLLO® SC OVICIDAL MITICIDE per hectare include:
1. Earliest seasonal timings for blocks with high overwintering European red mite egg populations.
2. When mite predator populations are low.
3. To ensure adequate coverage of full size standard trees and/or trees with heavy leaf densities.

and **replaced** with the following statements:

Target Species:
European red mite (*Panonychus ulmi*), Twospotted spider mite (*Tetranychus urticae*), McDaniel spider mite (*Tetranychus mcdanieli*).

Apply with ground equipment using air assist sprayer. Apply 300 mL APOLLO® SC OVICIDAL MITICIDE per hectare. Use sufficient volume of water to obtain complete coverage but not less than 475 litres per hectare. APOLLO® SC OVICIDAL MITICIDE works best when applied to eggs or young motile stages. It is not effective against adults.

Apples
APOLLO® SC OVICIDAL MITICIDE may be applied any time from delayed dormant through first cover. Best results in early season will be obtained if treatments are made at petal fall before mites hatch. Do not apply after first cover (provided first cover is not more than 14 days after petal fall). Do not apply within 21 days of harvest.

Pears
APOLLO® SC OVICIDAL MITICIDE may be applied early season (after delayed dormancy) through to summer. Apply at first sign of mite activity when mite populations are predominantly in the egg stage, with few early motiles (less than 3 per leaf). Do not apply within 21 days of harvest.